Listing of Claims:

1. (Currently Amended) An immediate-release pharmaceutical or nutraceutical micronized powder <u>for mucosal delivery of at least one active agent</u>, having a particle size of at most 100 μm and comprising:

- (a) at least one active substance;
- (b) at least one wetting agent;
- (c) at least one diluent; and
- (d) an antistatic agent comprising from 0.01 % to 10% by weight of the total weight of the composition;

wherein the powder has a dissolution kinetic of less than 30 seconds in an aqueous medium at pH 5 to 9, and

wherein, upon mucosal administration, the powder releases the active substance(s) at the mucosal site.

- 2. (Previously Presented) A powder according to claim 1, with a particle size of at most 50μm.
- 3. (Previously Presented) A powder according to claim 1, with a particle size of at most 10μm.
- 4. (Previously Presented) A powder according to claim 1, wherein the powder releases all of the active substance(s) in less than 30 seconds after mucosal administration.
- 5. (Previously Presented) A powder according to claim 1, wherein the active substance is in a micronized form.
- 6. (Currently Amended) A powder according to claim 1, wherein the active substance is at least one member selected from the group consisting of cyproterone acetate, norethisterone acetate, progesterone, 3-keto-desogestrel, norgestimate, laevonorgestrel levonorgestrel, desogestrel, gestodene, a natural estrogen, a synthetic estrogen, Δ -4-androstenedione, testosterone, dihydrotestosterone, androstanolone, DHEA, trinitrine,

fentanyl, nitroglycerine, nicotine, scopolamine, clonidine, isosorbide dinitrate, alclometasone dipropionate, phloroglucinol, molsidomine, acetazolamide, acyclovir, adapalene, alclomethasone dipropionate, amcinonide, ameline, bamethan sulphate in combination with escin, betamethasone valerate, betamethasone dipropionate, bufexamac, caffeine, calcipotriol monohydrate, cetrimonium bromide, clobetasol propionate, crilanomer, desonide, dexpanthenol, diclofenac, diflucortolone, valerate, difluprednate, diphenydramine hydrochloride, econazole nitrate, erythromicin, flumetasone pivalate, fluocinolone acetonide, fluocinodine, fluocortolone, fluocortolone hexanoate, fluocortolone pivalate, hydrocortisone, hydrocortisone acetate, ibacitabine, ibuprofen, imiquimod, ketoconazole, ketoprofen, lidocaine, metronidazole, miconazole nitrate, minoxidil, nifluminic acid, penciclovir, benzoyl peroxide, piroxam, iodinated povidone, promestriene, pyrazinobutazone, roxithromycin, sulphacetamide, triamcinolone, tazarotene, tretinoin and isotretinoin, triclocarban, vidarabine monophosphate, β -3-adrenergic agonist, growth hormone, oxybutinin, buprenorphine, pergolide, nestorone, 7a- methyl-19-nortesterone, mecamylamine, salbutamol, clenbuterol, selegiline, buspirone, ketotifen, lidocaine, ketorolac, eptazocine, insulin, a-interferon, prostaglandins, 5-aminolevulinic acid, benzodiazepine alprozolam, diclofenac, fenoprofen, flubiprofen, ketoprofen, methyl phenidate, miconazole, piroxicam, bruprenorphine, alprozolam, dexmedetomidine, prazosin, alprostadil, tulobuterol, ethinyl oestradiol in combination with norelgestromin, ketorolac, physostigmine, medindolol, rotigotine, thiatolserine, esomerprazole, melagatran, rosuvastatin, ezetimide, pitavastatin, mitiglinide, cilomilast, viozan, aripipazole aripiprazole, omapatrilat, orzel, caspofongin acetate, voriconazole, etoricoxib, valdecoxib, parecoxib, substance P antagonist, darifenacin, eletriptan, alosetron, tegaserod, capravirine, finasteride and combinations thereof.

- 7. (Previously Presented) A powder according to claim 1, wherein the active substance is at least one member selected from the group consisting of a vitamin, brewer's yeast, and a mineral salt that is approved for human consumption.
- 8. (Previously Presented) A powder according to claim 1, wherein the wetting agent is at lease one member selected from the group consisting of a polyol, triacetin, a

hydrogenated vegetable oil, a polyoxy(ethylene)polyoxy(propylene) copolymer and a polyoxyethylene alkyl ether.

9. (CurrentlyAmended) A powder according to claim 1, wherein the diluent is at least one member selected from the group consisting of calcium or sodium carbonate or bicarbonate, sucrose, mannitol, xylitol, sorbitol, lactose, maltotol, glucose, cellulose, a microcrystalline cellulose powder, starch, a starch derivative, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulphate, a dextrate, a dextrin, a dextrose, fructose, kaolin, and lactitol.

10. (Canceled)

- 11. (Previously Presented) A powder according to claim 1, wherein the antistatic agent is selected from the group consisting of colloidal silica, magnesium silicate, talc, calcium silicate and tribasic calcium phosphate, and mixtures thereof.
- 12. (Previously Presented) A powder according to claim 1, further comprising -a binder which comprises at least one member selected from the group consisting of acacia, alginic acid, carboxymethyl cellulose sodium, microcrystalline cellulose, a dextrin, ethyl cellulose, gelatin, glucose, guar gum, hydroxypropyl methyl cellulose, methyl cellulose, polyethylene oxide, povidone, and pregelatinized starch.
- absorption enhancer which comprises at least one member selected from the group consisting of an aliphatic fatty acid ester, a fatty acid, an alcohol or polyol, a component of an essential oil, a terpene derivative, eugenol, geraniol, nerol, eucalyptol, menthol, a surfactant, a moisturizer, a keratolytic agent, 23-lauryl ether, aprotinin, azone, benzalkonium chloride, cetylpyridinium chloride, cetyltrimethylammonium bromide, a cyclodextrin, dextran sulphate, lauric acid, lysophosphatidylcholine, a menthol, methoxysalicylate, methyl oleate, oleic acid, phosphatidylcholine, polyoxyethylene, polysorbate 80, sodium EDTA, sodium glycocholate,

sodium glycodeoxycholate, sodium lauryl sulphate, sodium salicylate, sodium taurocholate, sodium taurodeoxycholate, a sulphoxide, and an alkyl glycoside.

- 14. (Previously Presented) A powder according to claim 1, further comprising -an edulcorant agent and/or a flavoring agent.
- 15. (Previously Presented) A powder according to claim 14, wherein the edulcorant agent is selected from the group consisting of aspartam, dextrates, dextrose, fructose, mannitol, sodium or calcium saccharinate, sorbitol, sucralose, sucrose, and mixtures thereof.
- 16. (Previously Presented) A powder according to claim 14, wherein the flavoring agent is at least one member selected from the group consisting of a flavor of synthetic, semi-synthetic, or natural origin.
- 17. (Previously Presented) A powder according to claim 1, in a form suitable for its application on the buccal mucosa, the nasal mucosa, or the vaginal mucosa.
- 18. (Previously Presented) A powder according to claim 1, in a form suitable for its sublingual application to the buccal mucosa.
 - 19. (Previously Presented) A powder according to claim 1, in a sprayable form.
- 20. (Previously Presented) A powder according to claim 1, packaged in a single-dose packet.
- 21. (Previously Presented) A powder according to claim 1, packaged in a thermally moulded capsule provided with a peelable operculum.
- 22. (Previously Presented) A powder according to claim 1, provided in packaging suitable for administration of a powder.

- 23. (Canceled).
- 24. (Currently Amended) A powder according to claim 6, wherein the active substance is at least one member selected from the group consisting of estradiol, a natural estradiol derivative a natural estrogen, ethinylestradiol, and etoricoxib.
- 25. (Previously Presented) A powder according to claim 8, wherein the wetting agent is at least one member selected from the group consisting of PEG, hexylene glycol, triacetin, and a hydrogenated vegetable oil.
- 26. (Previously Presented) A powder according to claim 13, wherein the absorption enhancer is at least one member selected from the group consisting of isopropylmyristate, oleic acid, ethanol, propylene glycol, polyethylene glycol, eugenol, geraniol, nerol, eucalyptol, menthol, polyoxyethylene sorbitan, polyoxyethylene alkyl ether, polyoxyethylene derived from castor oil, glycerin, urea, and an alpha-hydroxy acid.
- 27. (Previously Presented) A method for manufacturing an immediate-release pharmaceutical or nutraceutical composition, comprising micronizing a composition comprising:
 - (a) at least one active substance;
 - (b) at least one wetting agent;
 - (c) at least one diluent; and
- (d) an antistatic agent comprising from 0.01 % to 10% by weight of the total weight of the composition.